IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC., Defendants.	C.A. No. 22-252-JDW
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	

MODERNA'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO EXCLUDE MR. PITTS' AND MR. BRILL'S EXPERT REPORTS

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I. INTRODUCTION[1]

Moderna respectfully moves to exclude Mr. Peter Pitts' and Mr. Alex Brill's expert reports either (1) in their entirety because expert evidence is unnecessary to resolve the statutory question of what satisfies the "for the Government" clause of 28 U.S.C. § 1498(a) or (2) at least certain portions of those reports that contradict stated Government-policy goals to support the COVID-19 pandemic. Mr. Pitts' and Mr. Brill's reports largely attempt to define what should or should not be a "benefit" "for the Government." This is not a question for a fact finder or expert to define but is rather a question of statutory interpretation. To allow experts to opine on this type of question opens the door to positions that contradict Congress's and the Executive's stated policy goals—e.g., to provide the COVID-19 vaccine to the Government as part "of the national emergency response to . . . COVID-19[], for the United States Government . . . and the US population." Ex. 1 (C-100 Contract) at C.1. Under this Court's authority as a gatekeeper to "ensure that any and all scientific testimony or evidence admitted is [both relevant and reliable]," Mr. Pitts' and Mr. Brill's testimony should be excluded. *EcoFactor, Inc. v. Google LLC*, 137 F.4th 1333, 1339 (Fed. Cir. 2025) (en banc) (cleaned up).

II. STATEMENT OF THE NATURE AND STAGE OF PROCEEDINGS

On February 28, 2022, Plaintiffs sued Moderna, accusing Moderna's COVID-19 vaccine of patent infringement. D.I. 1. Fact and expert discovery are closed.[2] Summary judgment briefing

[1] All emphasis added unless otherwise noted.

[2] Moderna is still engaging in a limited amount of expert discovery from Plaintiffs arising out of Moderna's Motion to Compel materials that were withheld by Plaintiffs' infringement testing expert, Dr. Georg Schuster, and ordered Judge Goldberg to be produced. D.I. 485.

is scheduled to complete on September 19, 2025, and *Daubert* briefing is scheduled to complete on December 5, 2025.[3] Trial is scheduled to begin March 9, 2026. D.I. 485.

III. SUMMARY OF ARGUMENT

(1) Plaintiffs' experts improperly opine on what constitutes a "benefit" to the Government under 28 U.S.C. § 1498. For at least two reasons, Mr. Pitts' and Mr. Brill's expert reports should be excluded under Federal Rule of Evidence 702 ("Rule 702"), which "governs the admissibility of expert testimony." *Ecofactor*, 137 F.4th at 1338. ***First***, what constitutes a "benefit" to the Government, thus satisfying the "for the Government" clause in § 1498, is a question of statutory interpretation (i.e., a question of law). *Sevenson Env't Servs., Inc. v. Shaw Env't, Inc.*, 477 F.3d 1361, 1365–66 (Fed. Cir. 2007). Expert testimony on the interpretation of a statute is impermissible. *E.g.*, *Ford v. Panasonic Corp. of N. Am.*, 284 F. App'x 901, 904 (3d Cir. 2008). Thus, the entirety of Mr. Brill's and Mr. Pitts' expert reports should be excluded. ***Second***, and alternatively, paragraphs 24–38, 41–42, 45, and 49–66 of Mr. Pitts' and paragraphs 17–20, 22–23, 25–38, 55, 65, and 68 of Mr. Brill's expert reports should be excluded because they opine on what ***should*** constitute a benefit to the Government, contradicting the Government's own stated policy goals. Such policy-based arguments are not for a fact finder to decide and reliance on these opinions contradicts Federal Circuit precedent that states a contract is "for the Government" when it is "in furtherance and fulfillment of a stated Government policy." *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014) (citation omitted). Thus, these opinions should be excluded under Rule 702.

[3] Moderna submits this motion to exclude pursuant to paragraph 6 of the Scheduling Order. D.I. 485 at 2–3. Moderna reserves all rights serve its *Daubert* motions in connection with the schedule set forth paragraph 7 of that same order. *Id.* at 3.

IV. STATEMENT OF FACTS

During the height of the COVID-19 pandemic in 2020, Moderna acted swiftly and tirelessly to provide the U.S. Government with a vaccine under the C-100 contract that in Plaintiffs' own words "saved countless lives." D.I. 1 at 21. "Under Operation Warp Speed (OWS), the Department of Defense and HHS [led] a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures" would be "available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people." Ex. 1 (C-100 Contract) at C.1.1.1. Pursuant to the C-100 contract, Moderna supplied hundreds of millions of doses of the COVID-19 vaccine to the Government as part "of the national emergency response to . . . COVID-19[], for the United States Government . . . and the US population." Ex. 1 (C-100 Contract) at C.1. These doses that the Government sought and received under this Contract represent roughly $2.5 billion of Plaintiffs' requested damages.

The C-100 Contract includes two FAR provisions, relevant here:

> FAR 52.227-1 states: "(a) [t]he Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent – (1) [e]mbodied in the structure or composition of any article the delivery of which is accepted by the Government under this contract; . . . ."
>
> FAR 52.227-1, Alternate I states: "(a) [t]he Government authorizes and consents to all use and manufacture of any invention described in and covered by a United States patent in the performance of this contract or any subcontract at any tier."

Ex. 1 (C-100 Contract) at 46 (48 CFR § 52.227-1; 48 CFR § 52.227-1, Alt. I). Together, these FAR provisions represent the standard contractual clauses that the U.S. Government includes to incorporate the statutory provisions of 28 U.S.C. § 1498. Section 1498(a) states:

> "Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof . . . the owner's remedy shall be by action against the United States in the United States Court of Federal Claims . . . .
>
> [T]he use or manufacture of an invention described in and covered by a patent of the United States by a contractor, . . . ***for the Government and with the authorization or consent of the Government***, shall be construed as use or manufacture for the United States."

28 U.S.C. § 1498(a).

In February 2022, Plaintiffs sued Moderna, alleging Moderna's COVID-19 vaccine infringes six patents. D.I. 1 ¶ 9. In May 2022, Moderna filed a partial motion to dismiss Plaintiffs' allegations subject to § 1498, which provides a shield to Government contractors for alleged patent infringement when the accused infringing activity is "for the Government and with the authorization or consent of the Government." 28 U.S.C. § 1498(a) (above); D.I. 17. Specifically, Moderna moved to dismiss "Plaintiffs' claims based on Moderna's sale and provision of COVID-19 Vaccine doses to the U.S. Government" under the C-100 Contract. D.I. 17 at 14. That motion was denied, and the Court stated, "[a]bsent clear language, either in the Complaint or the Contract, establishing that the development of the vaccine was 'for the Government,' I find that this dispute is not appropriate for resolution in a Rule 12(b)(6) motion." D.I. 31 at 13, 16. A few months later, the Government filed a Statement of Interest in this case, stating that it accepted liability pursuant to the C-100 Contract, D.I. 49 at 1, and agreed that the C-100 Contract was "for the benefit" and "with the authorization and consent of the Government," *id.* at 7, 9–10. In light of the Government's Statement of Interest, this Court reconsidered the application of § 1498 at the motion to dismiss stage but ultimately denied reconsideration. The Court reasoned that "[w]hile the Statement of Interest does point to certain evidence that Moderna's sales under the [C-100] Contract may have been with the 'authorization and consent' of the Government, Moderna offers no evidence that sales were 'for the Government' which is also a necessary factor under

§ 1498(a)." D.I. 64 at 3. The Court instead stated that "[d]iscovery is necessary to ensure that any application of § 1498(a) is based upon developed facts and not solely on the Government's say-so." *Id.*

With fact and expert discovery closed, Moderna now moves for summary judgment under § 1498, asking that Plaintiffs' claims against Moderna for doses provided to the Government pursuant to the C-100 Contract be dismissed. In light of § 1498, if Plaintiffs believe those doses infringe a valid patent(s), their ***sole means of recovery*** for any alleged infringement of those doses is in the U.S. Court of Federal Claims and against another party. *See* 28 U.S.C. § 1498(a). Although the C-100 Contract itself should be dispositive in Moderna's favor as to the § 1498 inquiry, to the extent the Court disagrees, Moderna also submitted expert reports offering epidemiological and economic opinions that explained how the vaccine under the Contract provided benefits to the Government in furtherance of the Government's stated policy goals. In response, Plaintiffs submitted rebuttal expert reports by Mr. Pitts and Mr. Brill. But those reports go well beyond opining on whether a benefit to the U.S. Government exists with respect to Moderna's COVID-19 vaccine and pursuant to the C-100 Contract and instead attempts to redefine what constitutes a "benefit" to the Government. Having redefined the meaning of a "benefit," Mr. Pitts and Mr. Brill reached extreme conclusions—e.g., that the Government did not benefit from the doses of the COVID-19 vaccine, Ex. 62 (2025-02-14 Brill Rebuttal Rep.) ¶ 18, and that "deaths from [COVID-19] may reduce spending more than they reduce taxes" and thus increase the economic benefit to the government, *id.* ¶ 50.

V. LEGAL STANDARD

"Federal Rule of Evidence 702 governs the admissibility of expert testimony." *Ecofactor*, 137 F.4th at 1338. Rule 702 states, in relevant part, that "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or

otherwise if the proponent demonstrates to the court that it is more likely than not that: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue . . . ." Fed. R. Evid. 702(a). "This condition goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993) (cleaned up).

VI. ARGUMENT

Under § 1498, a plaintiff must bring its patent infringement allegations against the United States in U.S. Court of Federal Claims "if two criteria are met: (1) the use is 'for the Government'; and (2) the use is 'with the authorization and consent of the Government.'"[4] *Sevenson*, 477 F.3d at 1365 (citation omitted). "[T]he 'for the Government' prong of the definition appears to impose only a requirement that the use or manufacture . . . occur pursuant to a contract with the government and ***for the benefit of the government***." *Id.* at 1366.

A. The "For the Government" Prong of § 1498 Involves a Legal Question—Not a Fact Question Requiring Expert Testimony.

When "the government sought and received . . . services" "the infringing method was practiced 'for the Government'"—i.e., for the benefit of the Government. *Id.* In *Sevenson*, the Federal Circuit confirmed that what constitutes a "benefit for the Government" is a legal question of statutory interpretation—not a factual one. *Id.* (concluding plaintiffs' "factual arguments" "fail" and are "irrelevant"); *see also Merck Sharp & Dohme B.V. v. Aurobindo Pharma USA, Inc.*, 130 F.4th 1363, 1368 (Fed. Cir. 2025) ("Statutory construction is a question of law . . . ."). It is inappropriate for experts, like Mr. Pitts and Mr. Brill, to opine on questions of statutory

[4] The second prong, "with the authorization and consent of the Government," is not disputed in this motion.

interpretation, just as it would be improper to send interpretive disputes to the jury. *See, e.g.*, *In re Downey Fin. Corp.*, 593 F. App'x. 123, 126 n.3 (3d Cir. 2015) ("The . . . Declaration was inadmissible because contract interpretation is a legal question for which the court does not require expert opinion." (citation omitted)); *Ford*, 284 F. App'x at 904 ("[T]he experts' dispute was irrelevant . . . because the experts were offering their interpretations about what the guidelines meant, which interpretation a court may just as easily undertake to carry out without the assistance of expert testimony."); *Cryovac Inc. v. Pechiney Plastic Packaging, Inc.*, 430 F. Supp. 2d 346, 364 (D. Del. 2006) ("[T]estimony on substantive areas of patent or contract law is impermissible."); *Allscripts Healthcare, LLC v. Andor Health, LLC*, 2022 WL 3021560, at *44 (D. Del. July 29, 2022) ("It is well-established 'the law of contract interpretation . . . firmly prohibits expert testimony as to legal duties, standards or ramifications arising from a contract.' An expert may not opine regarding 'the scope and meaning' of a contract." (citations omitted)).

B. To The Extent Any Factual Arguments Are Relevant, Unlike Plaintiffs' Expert Opinions, Government "Benefits" are Limited to Those Which Further The Government's Stated Policy Goals

In cases where the accused goods are not sold pursuant to a Government contract with express authorization and consent (unlike the C-100 Contract here), Courts consider "if it is 'in furtherance and fulfillment of a stated Government policy' which serves the Government's interests and which is 'for the Government's benefit.'" *IRIS*, 769 F.3d at 1362 (citation omitted). Many parts of Mr. Pitts' and Mr. Brill's reports do not opine on whether the contract is "in furtherance and fulfillment of a stated Government policy," but instead, they express their own opinion on *what constitutes a benefit* to the Government untethered from any stated policy goals. Those opinions are unhelpful to the trier of fact because what constitutes a benefit is not a factual question for the jury to resolve, and thus, paragraphs 24–38, 41–42, 45, and 49–66 of Mr. Pitts'

and paragraphs 17–20, 22–23, 25–38, 55, 65, and 68 of Mr. Brill's expert reports should be excluded.

Here, in the C-100 Contract itself, the Government explained its policy goals under Operation Warp Speed as the following: "to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures are available in the quantities required," and "the USG supports large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained." Ex 1 (C-100 Contract) at C.1.1.1. In other words, the Government's goals were to obtain sufficient availability of vaccines and mitigate risk if certain manufacturers had challenges manufacturing the vaccine. Multiple sources throughout the Executive and Legislative branches of government repeated these goals. *See, e.g.*, Ex. 30-B (2025-03-21 Rutherford Reply Rep.) ¶¶ 23–30.

Mr. Pitts and Mr. Brill do not dispute that Moderna's vaccine had significant benefits. Instead, they argue those benefits were not for the Government and attempt to redefine what is a benefit for the Government. For example, many arguments in Mr. Brill's report revolve around a dispute as to what types of "benefits" count. Section IV of his report opines on the uncertainty of the economic benefit to the Government and the uncertainty of the efficacy of the vaccine at the time of the C-100 Contract. Ex. 62 (2025-02-14 Brill Rebuttal Rep.) ¶¶ 23–29. But the Government recognized this uncertainty in the C-100 Contract, and the Contract still furthered its policy goals for the vaccine to be "***immediately available for nationwide access as soon as a positive efficacy*** signal is obtained and the medical countermeasures are authorized for widespread use." Ex. 1 (C-100 Contract) at C.1.1.1. Moreover, a level of uncertainty nearly always exists in medical research, thus Mr. Brill's argument would foreclose § 1498 from ever applying in these circumstances—a

carve out that plainly does not exist in the statute. Section V asserts that budget impacts are not a "benefit" to the Government, but whether a positive net budgetary impact is a benefit is not for a fact finder to decide. Ex. 62 (2025-02-14 Brill Rebuttal Rep.) ¶¶ 31–38.

Likewise, Section IV of Mr. Pitts' report largely argues that the Government did not benefit from the COVID-19 vaccine, but instead the American public did. Ex. 63 (2025-02-14 Pitts Rebuttal Rep.) ¶¶ 29–38. But this contradicts the Government's stated goal to provide the vaccine to "mitigate[e] the impact of COVID-19 on the nation and its people." Ex. 1 (C-100 Contract) at C.1.1.1. Moreover, that the vaccine also has a benefit to the general public (in addition to the Government), does not take away from the benefit to the Government. *See Sevenson*, 477 F.3d at 1365 (explaining that the Government's benefit need not be the "primary purpose" and the Government need not be the sole beneficiary). As another example, Section V of Mr. Pitts' report puts significant emphasis on to ***whom*** the Government provided the vaccines it purchased. Ex. 63 (2025-02-14 Pitts Rebuttal Rep.) ¶¶ 49–58. But the Government's decision to distribute vaccines ***it purchased and received via a contract*** to downstream distributors is also irrelevant. That the Government used various downstream distributors to deliver the vaccine does not contradict the Government's goal of supplying the vaccine to the American people. Section VI of Mr. Pitts' report frets about the "consequences" of applying § 1498 to the Government's purchase of COVID-19 vaccines, but whether good or bad consequences result from the C-100 Contract and/or applying § 1498 to C-100 Contract is not a policy question for a fact finder—that question is left to Congress. Ex. 63 (2025-02-14 Pitts Rebuttal Rep.) ¶¶ 59–66.

VII. CONCLUSION

For the reasons above, Mr. Pitts' and Mr. Brill's expert reports should be excluded in their entirety, or at the very least, paragraphs 24–38, 41–42, 45, and 49–66 of Mr. Pitts' and

paragraphs 17–20, 22–23, 25–38, 55, 65, and 68 of Mr. Brill's expert reports should be excluded as improper expert testimony.

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July 25, 2025

CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2025, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 1, 2025, upon the following in the manner indicated:

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